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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,029	08/27/2003	Jeffrey M. Ondra	DEP5108USA	6457
27779 7590 08/17/2009 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				
EXAMINER				
BLANCO, JAVIER G				
ART UNIT		PAPER NUMBER		
3774				
MAIL DATE		DELIVERY MODE		
08/17/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/650,029

Applicant(s)

ONDRLA ET AL.

Examiner

JAVIER G. BLANCO

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9,11,12,15-17,19,21-24,27-31 and 41 is/are pending in the application.

4a) Of the above claim(s) 41 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,2,5-9,11,12,15-17,19,21-24 and 27-31 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2009 has been entered.

Response to Amendment

2. Applicants' amendment of claims 1, 11, and 21 in the reply filed on May 27, 2009 is acknowledged.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5, 6-9, 11, 12, 15-17, 19, 21-24, 27-29, and 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Siebrandt** (US 2,181,746).

Referring to Figures 1-5, Siebrandt discloses a positioning fixture *for positioning* at least one of a trial and a prosthesis in the medullary canal of a long bone, said fixture comprising or

consisting essentially of: a body (12/14); a first member (pin 27) member *for cooperation* with the body, said member extending from said body and *adapted to extend* through at least a portion of the long bone (see Figures 2 and 5) and into the medullary canal; second (20) and third (29) members (which are spaced a distance from the first member), any of said members *adapted to support* (capable of supporting) at least one of the trial and the prosthesis as the one of the trial and the prosthesis is positioned with respect to the long bone (see page 2, second column, lines 67-75); and a securing feature (15) cooperable with said body (12/14); said body comprising a crescent-shaped member (clearly visible in Figure 4, when clamp is open) *for at least partially surrounding* the long bone (see Figures 2 and 5), the crescent-shaped member comprising a first portion (12) and a second portion (14) moveably attached (16) to said first portion, the first portion and the second portion both being shaped so as to create a crescent. Regarding dependent claim 2, no structure is offered therein since the entire claim only offers a functional limitation. Any of the members disclosed above is capable of permitting relative relative motion between the body and the one of least one of the trial and the prosthesis (the trial and prosthesis are not positively claimed in independent claims 1 and 11) as the one of the trial and the prosthesis cooperates with said member. The “securing feature” could be the inner/inside wall of the body, which frictionally engages (“for securing”) the fixture to the long bone. If a person skilled in the art continues turning (e.g., screwing) a pin or screw into a bone it will eventually be adapted to extend through the cortical bone and into the medullary canal.

Regarding independent claim 21, the structure of the “trial” (one of the options offered by “one of a trial and a prosthesis”) has not been disclosed. Siebrandt discloses a “trial” (e.g., wire, suture; further drill bits, etc.) at page 2, second column, lines 67-75. The “cooperation feature” is

the outside/external periphery of the "trial". Further, structure 28 can also be broadly interpreted as the "trial", which comprises a "cooperation feature" (26) slidably receiving a "first member" (27).

The first portion (12) and second portion (14) being connected (directly or indirectly) via a thumbwheel (17 and/or 43), the thumbwheel *adapted to lock* the first portion relative to the second portion, the thumbwheel being located at a pivot centerline (16 and/or 11) of the body. Further, the use of a thumbwheel to connect moving parts is already well known in the art, and would have been obvious for the advantage of adjusting/holding a first part and a second part in a particular position relative to each other.

With regards to statements of intended use and other functional statements (e.g., *for positioning; adapted to extend; adapted to support; for at least partially surrounding; adapted to permit; adapted to lock; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Siebrandt**, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

5. Claims 1, 2, 5-9, 11, 12, 15-17, 19, 21-24, and 27-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Maroney et al.** (US 6,277,123 B1).

Referring to Figures 1-7, Maroney et al. disclose a positioning fixture (clamp 20, or clamps 20/50) *for positioning* at least one of a trial and a prosthesis in the medullary canal of a long bone (see Abstract), said fixture comprising or consisting essentially of: a body (**first interpretation:** a pair of jaws 21; **second interpretation:** central portion 11); a first member (pin 17) member *for cooperation* with the body, said member extending from said body and *adapted to extend* through at least a portion of the long bone and into the medullary canal (**first interpretation:** along the medullary canal and into, or through, the bone; **second interpretation:** if a bore is created transversely through the cortical bone, pin 17 will be adapted to extend through at least a portion of the long bone; **third interpretation:** if a person skilled in the art continues turning (e.g., screwing) a pin or screw into a bone it will eventually be adapted to extend through the cortical bone and into the medullary canal); second and third members (22, 40, 52, and/or 54) which are spaced a distance from the first member, any of said members *adapted to support* (capable of supporting, directly or indirectly) at least one of the trial and the prosthesis as the one of the trial and the prosthesis is positioned with respect to the long bone (see Figures 1-5); and a securing feature (e.g., serrations in jaws 21) cooperable with said body; said body comprising a crescent-shaped member (clearly visible in Figures 1, 1a, 5, and 6) *for at least partially surrounding* the long bone (see Figures 1-5), the crescent-shaped member comprising a first portion (**first interpretation:** a jaw 21; **second interpretation:** upper arms 12) and a second portion (**first interpretation:** the other jaw 21; **second interpretation:** lower

arms 12) moveably attached (clearly visible in Figures 1, 1a, 5, and 6) to said first portion, the first portion and the second portion both being shaped so as to create a crescent. Regarding dependent claim 2, no structure is offered therein since the entire claim only offers a functional limitation. Any of the members disclosed above is capable of permitting relative relative motion between the body and the one of least one of the trial and the prosthesis (the trial and prosthesis are not positively claimed in independent claims 1 and 11) as the one of the trial and the prosthesis cooperates with said member (further shown in Figures 1-5). Regarding the "cooperation feature" it is either the outside/external periphery of the "trial" and/or prosthesis, OR holes 65 (as shown in Figure 7) slidably receiving pins of 52, 54. The "securing feature" could be the inner/inside wall of the body, which frictionally engages ("for securing") the fixture to the long bone.

The first portion and second portion being connected (directly or indirectly) via a thumbwheel (**first interpretation:** 17a and/or 17b; **second interpretation:** head of pin 17 is a thumbwheel), the thumbwheel *adapted to lock* the first portion relative to the second portion, the thumbwheel being located at a pivot centerline of the body. Further, the use of a thumbwheel to connect moving parts is already well known in the art, and would have been obvious for the advantage of adjusting/holding a first part and a second part in a particular position relative to each other.

With regards to statements of intended use and other functional statements (e.g., *for positioning; adapted to extend; adapted to support; for at least partially surrounding; adapted to permit; adapted to lock; etc.*), they do not impose any structural limitations on the claims distinguishable over the device of **Maroney et al.**, which is capable of being used as claimed if

one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

6. Claims 1, 2, 5-9, 11, 12, 15-17, 19, 21-24, and 28-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Kenyon et al.** (US 5,342,362 A).

Referring to Figures 1-4, 7, 10, and 11, Kenjon et al. disclose a positioning fixture (adaptor 30 and/or indicator 110) *for positioning* at least one of a trial and a prosthesis in the medullary canal of a long bone, said fixture comprising or consisting essentially of:

- a. A body (**Figures 7, 10 and 11**: assembly comprising clamp 124); and
- b. Members (**Figures 7, 10 and 11**: anchor pin 96) *for cooperation* with the body.

As shown in Figures 7, 10, and 11, the body comprising a crescent-shaped member (e.g., clamp 124) and is capable of at least partially surrounding the long bone. Said member extending from said body and *adapted to extend* through at least a portion of the long bone and into the medullary canal, said member *adapted to support* at least one of the trial (see Figure 10) and the prosthesis (see Figure 11) as the one of the trial and the prosthesis is positioned with respect to

the long bone. Said one of said trial and said prosthesis including a cooperation feature (**Figures 7, 10 and 11**: transversal grooves and/or longitudinal grooves on stem 6, 100). As shown in Figures 7, 10, and 11, the “first portion” is one end (or one half) of the body, and the “second portion” is the other end (or other half) of the body, wherein one end/half is “movably attached” to the other end/half (**first interpretation**: “if one portion moves, the other portion moves as well”; **second interpretation**: there is a natural hinge in the middle of the crescent, in between both portions; **third interpretation**: portions are “movably attached” at ends connected by wing nut). Also, housing 32 comprises leg 35 and arm 36 (see Figures 1-3). The “securing feature” could be the inner/inside wall (or an external portion or surface) of the body, which frictionally engages (“for securing”) the fixture to the long bone. Also, the “securing feature” could be nipples 48 and/or arms 44,46 (Figures 1-3) or connection port 116 (Figures 7, 10, and 11).

The first portion (e.g., first half of crescent) and second portion (e.g., second half of crescent) being connected (directly or indirectly) via a thumbwheel (the wing nut is a “thumb wheel”), the thumbwheel *adapted to lock* the first portion relative to the second portion, the thumbwheel being located at a pivot centerline (for hinging area to connecting area) of the body. Further, the use of a “thumbwheel” (e.g., screw, wing nut, etc.) to connect moving parts is already well known in the art, and would have been obvious for the advantage of adjusting/holding a first part and a second part in a particular position relative to each other.

With regards to statements of intended use and other functional statements (e.g., *for positioning; adapted to extend; adapted to support; for at least partially surrounding; adapted to permit; adapted to lock*; etc.), they do not impose any structural limitations on the claims distinguishable over the device of **Kenyon et al.**, which is capable of being used as claimed if

one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

7. With regards to the 102(b) rejection based on **Siebrandt** (US 2,181,746), Applicants’ arguments filed May 27, 2009 have been fully considered but they are not persuasive.

With regards to each of independent claims 1, 11, and 21, the Applicants argue: “*Claim 1 has been amended to recite that the positioning feature is consisting essentially of the elements listed in the claim: a body and at least one body. Siebrandt does not disclose such an invention*”. The Examiner respectfully disagrees. According to M.P.E.P 2111.03: “A ‘**consisting essentially of**’ claim occupies a middle ground between closed claims that are written in a **consisting of**’ format and fully open claims that are drafted in a **comprising**’ format.” *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998)” AND “For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to

“comprising.” See, e.g., **PPG, 156 F.3d at 1355, 48 USPQ2d at 1355**. Therefore the Examiner is broadly interpreting “consisting essentially” as equivalent to “comprising”. The applied Prior Art of Record clearly defines the presence and structure of a “body” and “at least one member”.

8. With regards to the 102(b) rejection based on **Maroney et al.** (US 6,277,123 B1), Applicants’ arguments filed May 27, 2009 have been fully considered but they are not persuasive.

With regards to each of independent claims 1, 11, and 21, the Applicants argue: *“Claim 1 has been amended to recite that the positioning feature is consisting essentially of the elements listed in the claim: a body and at least one body. Maroney do not disclose such an invention.”*. The Examiner respectfully disagrees. According to M.P.E.P 2111.03: **“A ‘consisting essentially of’ claim occupies a middle ground between closed claims that are written in a consisting of’ format and fully open claims that are drafted in a comprising’ format.”** **PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998)**” AND **“For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.”** See, e.g., **PPG, 156 F.3d at 1355, 48 USPQ2d at 1355**. Therefore the Examiner is broadly interpreting “consisting essentially” as equivalent to “comprising”. The applied Prior Art of Record clearly defines the presence and structure of a “body” and “at least one member”.

9. With regards to the 102(b) rejection based on **Kenyon et al.** (US 5,342,362 A), Applicants' arguments filed May 27, 2009 have been fully considered but they are not persuasive.

With regards to each of independent claims 1, 11, and 21, the Applicants argue: "*Claim 1 has been amended to recite that the positioning feature is consisting essentially of the elements listed in the claim: a body and at least one body. Kenyon et al. do not disclose such an invention.*". The Examiner respectfully disagrees. According to M.P.E.P 2111.03: "A '**consisting essentially of**' claim occupies a middle ground between closed claims that are written in a **consisting of** format and fully open claims that are drafted in a **comprising**' format." **PPG Industries v. Guardian Industries**, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998)" AND "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "**consisting essentially of**" will be construed as equivalent to "**comprising**." See, e.g., **PPG**, 156 F.3d at 1355, 48 USPQ2d at 1355". Therefore the Examiner is broadly interpreting "consisting essentially" as equivalent to "comprising". The applied Prior Art of Record clearly defines the presence and structure of a "body" and "at least one member".

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Longfellow (US 2,087,722 A); **Grosso** (US 2,443,106 A); **Riniker** (US 3,727,610 A); **Janowski et al.** (US 6,860,883 A1); and **Caffiniere** (FR 2 651 993 A1).

11. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on **(571)272-4749**. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/

Examiner, Art Unit 3774

/David H Willse/

Primary Examiner, Art Unit 3738